REMARKS

The present communication responds to the Office Action dated May 5, 2005. In that Office Action, the Examiner rejected each of the pending claims. The rejections are respectfully traversed at least because none of the cited references disclose "a cannula cover for an injector, wherein said cover can be axially retracted prior to injection to expose a cannula and the cannula cover exhibits a substantially closed front facing side comprising a cannula passage opening," as recited by claim 1, as amended.

Rejection Under 35 U.S.C. § 102

Claims 1-4, 12, 16 and 17 were rejected under 35 U.S.C.§ 102(b) as being anticipated by U.S. Patent 5,559,318 to Sweeney et al. This rejection is traversed at least for the following reasons.

Sweeney et al. disclose a needle shield assembly having a releasable lock. As can be seen in Figures 1, 3, and 4, the needle shield lifts to expose the needle:

> Needle shield 35 is capable of rotating back and forth between a first needle protection position, as illustrated in FIG. 1 wherein needle cannula 21 is within longitudinal opening 41 of the needle shield, to a second position, such as the positions illustrated in FIGS. 3 and 4, exposing at least distal end 23 of the needle cannula. *Sweeney et al., Column 4, lines 23-28.*

As illustrated in Figures 1-4, the shield begins in a position extending axially along the needle. To expose the needle, the shield is rotated to extend axially in a direction opposite from the original position. The rotation is illustrated in Figures 2 and 3 and is transverse to the needle with the shield essentially pivoting at the base of the needle. The shield is not retracted axially to expose the needle.

At least because Sweeney et al. do not disclose a cannula cover wherein the cover can be axially retracted to expose a cannula, as recited by amended claim 1, it is respectfully submitted that Sweeney et al. do not anticipate claims 1-4, 12, 16, and 17. Reconsideration and allowance are thus respectfully requested.

Rejections Under 35 U.S.C. § 103

Sweeney et al. in view of Geist

Claims 5 and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sweeney et al. in view of U.S. Patent 6,413,243 to Geist. This rejection is traversed at least for the following reasons.

As discussed above with respect to the rejection of claims 1-4, 12, 16, and 17 as anticipated by Sweeney et al., Sweeney et al. teaches a shield that rotates transversely to expose the needle. Sweeney et al. do not disclose a cannula cover wherein the cover can be axially retracted to expose a cannula, as recited by amended claim 1.

Geist teaches an apparatus for covering a used hypodermic syringe needle. The apparatus includes a pair of covers mounted movably to the base and at least one latching member mounted on the base. The apparatus is intended for covering a needle after it has been used and is not configured for exposing the needle for use. Indeed, Geist provides an alternate cover which is removed prior to use:

> While not shown in FIG. 4A, it will be understood that as known to the art and as is conventional, the syringe needle 12 would come covered with a removable protective sleeve (not shown) which is removed to place the syringe needle in the exposed condition shown in FIG. 4A. *Geist, Column 3, lines 6-11.*

Further, the apparatus pivots about the needle and can not be axially retracted to expose a cannula:

> With the apparatus 10 of the present invention in place as shown in FIG. 4A, the syringe 14 and syringe needle 12 would be used by the health care provider, as described above, to take a blood sample from a patient or to inject a patient with a liquid medication and, after the syringe needle has been used, the syringe needle 12 would be withdrawn from the patient and the health care provider, for example would apply an upwardly acting force to one of the respective covers 22 or 24, as indicated by the arrows 27 and 28 in FIGS. 4B and 4C, to pivot the covers upwardly towards each other and towards the used syringe needle 12 until the covers 22 and 24 are pivoted together in a closed position over the used syringe needle 12 as shown in FIG. 4D to cover the needle and prevent the used syringe needle from causing any accidental skin puncture of the health care provider's skin, or the skin of another person. *Geist, Column 3, lines 11-26.*

Accordingly, Geist does not disclose, teach, or suggest "a cannula cover wherein the cover can be axially retracted to expose a cannula," as recited by amended claim 1.

As neither Sweeney et al. nor Geist, alone or in combination, disclose, teach, or suggest, "a cannula cover wherein the cover can be axially retracted to expose a cannula," as recited by amended claim 1, it is respectfully submitted that claims 5 and 6, each of which depend indirectly from claim 1, are patentable over the combination of Sweeney et al. and Geist. Accordingly, reconsideration and allowance are respectfully requested.

Sweeney et al. in view of Galli

Claims 7-11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sweeney et al. in view of U.S. Patent 5,681,291 to Galli. This rejection is traversed at least for the following reasons.

As discussed above with respect to the rejection of claims 1-4, 12, 16, and 17 as anticipated by Sweeney et al., Sweeney et al. teaches a shield that rotates transversely to expose the needle. Sweeney et al. do not disclose a cannula cover wherein the cover can be axially retracted to expose a cannula, as recited by amended claim 1.

Galli discloses an auto-injector including a slider covering a needle wherein the slider is positioned against a user's body with the needle entering the body and injection occurring as a result of a lower end of the slider being positioned against the user's body:

> The above is arranged in such a way that during the injection, with the bottom of the needle device slider bearing against the user's body, the thrust exerted by the user on the unit and transmitted to the syringe carring body must reach in order to allow the needle coming out, a force enough high to win the resistance of the resilient detent ring, of the needle device, to enlarge; enlargement which allows said ring to escape its seat and to snap over the annular projection formed on the syringe carrying body, thus instantly releasing all the energy accumulated in the user's hand and causing the needle device slider to snap upward uncovering the needle which therefore penetrates with predetermined optimal speed and force depending on the mechanical and elastic characteristics of the needle device detent ring.
>
> At the end of its upward movement, and therefore only when the needle penetration is completed, the upper edge of the slider reaches the injection device

> control sleeve, forcing it to move upwards and therefore allowing the free expansion of the injection device expansible detent ring and the release of the injection device piston which, under the thrust of the stressed spring, pushes the syringe piston and causes the medicament outlet. *Galli, Column 3, lines 12-27.*

As set forth above, the slider is retracted during insertion of the needle into the user's body and does not completely expose the needle until the needle penetration is complete.

The applicants thus respectfully submit that neither Sweeney et al. nor Galli, alone or in combination, disclose, teach, or suggest "a cannula cover wherein said cover can be axially retracted prior to injection to expose a cannula and the cannula cover exhibits a substantially closed front facing side comprising a cannula passage opening," as recited by claim 1, as amended. As each of claims 7-11 depend indirectly from claim 1, reconsideration and allowance are respectfully requested.

Sweeney et al. in view of D'Alessio et al.

Claims 13-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sweeney in view of U.S. Patent 5,984,899 to D'Alessio et al. This rejection is traversed at least for the following reasons.

As discussed above with respect to the rejection of claims 1-4, 12, 16, and 17 as anticipated by Sweeney et al., Sweeney et al. teaches a shield that rotates transversely to expose the needle. Sweeney et al. do not disclose a cannula cover wherein the cover can be axially retracted to expose a cannula, as recited by amended claim 1.

D'Alessio et al. discloses a needle protector device which is unlockable during actuation. The needle can not be exposed until actuation occurs:

> These features provide safer actuation and permit a simple, effective, and relatively inexpensive manner of assembly ... The device is safer to operate, since it does not require arming by rotating the cover with respect to the mount which requires placing the hand close to the opening through which the needle extends. Operation is simpler in that the device needs only to be placed against a needle-receiving surface before actuating the device. The device is safer in that actuation requires simultaneously pushing the device against the needle-receiving surface and turning the mount with respect to the cover, thereby reducing the likelihood of inadvertent actuation. Notably, actuation cannot occur unless the device is

compressed against the action of the spring, i.e., by placing it against a needle-receiving surface. *D'Alessio et al., Column 4, lines 1-16.*

Accordingly, D'Alessio et al. do not disclose, teach, or suggest, at least, a cover that can be retracted prior to injection, as recited by claim 1, as amended.

The applicants thus respectfully submit that neither Sweeney et al. nor D'Alessio et al., alone or in combination, disclose, teach, or suggest "a cannula cover wherein said cover can be axially retracted prior to injection to expose a cannula and the cannula cover exhibits a substantially closed front facing side comprising a cannula passage opening," as recited by claim 1, as amended. As each of claims 13-15 depend indirectly from claim 1, reconsideration and allowance are respectfully requested.

Conclusion

No additional claim fees are generated by this response. However, a petition to extend the time to respond is being submitted herewith, and the Office is hereby authorized to charge any additional fees, or credit any overpayment, associated with this communication or the petition to Deposit Account 04-1420.

This application now stands in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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